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### **REMARKS**

This is a full and timely response to the outstanding final Office Action mailed October 3, 2006. Through this response, claims 1, 3, 7, 10, and 12 have been amended; claims 5 and 9 have been canceled without prejudice, waiver, or disclaimer; and claims 14 and 15 have been added. Reconsideration and allowance of the application and pending claims are respectfully requested.

#### **I. Claim Rejections - 35 U.S.C. § 102(b)**

##### **A. Statement of the Rejection**

Claims 1-2 and 6 have been rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by *Steiner et al.* ("Steiner," U.S. Pat. No. 5,499,984). Applicant respectfully traverses this rejection and through amendments to claim 1 consider these rejections moot as to claims 1-2 and 6.

##### **B. Discussion of the Rejection**

It is axiomatic that "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983). Therefore, every claimed feature of the claimed invention must be represented in the applied reference to constitute a proper rejection under 35 U.S.C. § 102(b).

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In the present case, not every feature of the claimed invention is represented in the *Steiner* reference. Applicant discusses the *Steiner* reference and Applicant's claims in the following.

Claim 1 recites (Emphasis added):

1. A flexible tap apparatus member comprising:  
***a shaft having a first passage disposed axially therein, a second passage communicating with and extending outwardly from said first passage to an outer surface of said shaft, a flexible upper shaft portion, and a flexible lower shaft portion;***  
said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface; and  
***a dye;***

wherein said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in a tissue; and

***wherein said first passage and said second passage are sized and shaped to communicate said dye to the tissue into which the upper shaft portion is anchored.***

Applicant respectfully submits that the rejection of independent claim 1 and the respective dependent claims under this rejection have been rendered moot. Further, as to the amended claim 1, Applicant respectfully submits that *Steiner* fails to disclose, teach, or suggest at least the above emphasized claim elements.

The Office Action, page 2, alleges that *Steiner* discloses "a flexible tap apparatus member (20, 30) including a flexible upper shaft portion including ridges 21 and a flexible lower shaft portion that is coupled to an adapter or "handle" 33 (Figs. 1 and 10, col. 2, lines 31-67, col. 4, lines 1-50 and col. 5, lines 41-47)." Applicant respectfully disagrees.

Applicant respectfully submits that *Steiner* fails to disclose a flexible upper shaft portion as claimed. It appears that *Steiner* discloses a flexible lower shaft and a rigid cutting head 20. The Office Action, page 3, includes Fig. 1 of *Steiner* with

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notations by the Examiner. Applicant respectfully submits that the cutting head 20 that is marked by the Examiner as "Flexible Upper Shaft Portion" does not appear to be flexible because *Steiner* offers no disclosure of a flexible cutting head or a "flexible upper shaft portion" as claimed.

Additionally, it does not appear that *Steiner* discloses a second passage communicating with and extending outwardly from said first passage to an outer surface of said shaft or a dye.

Due to the shortcomings of the *Steiner* reference described in the foregoing, Applicant respectfully assert that *Steiner* does not anticipate Applicant's claims. Therefore, Applicant respectfully requests that the rejection of these claims be withdrawn.

Because independent claim 1 is allowable over *Steiner*, dependent claims 2 and 6 are allowable as a matter of law for at least the reason that the dependent claims 2 and 6 contain all elements of their respective base claim. See, e.g., *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

## II. Claim Rejections - 35 U.S.C. § 102(e)

### A. Statement of the Rejection

Claims 1-6 have been rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by *Boucher et al.* ("*Boucher*," U.S. Pat. No. 6,716,216). Applicant respectfully traverses this rejection.

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**B. Discussion of the Rejection**

Claim 1 recites (Emphasis added):

1. A flexible tap apparatus member comprising:  
a shaft having a first passage disposed axially therein, **a second passage communicating with and extending outwardly from said first passage to an outer surface of said shaft**, a flexible upper shaft portion, and a flexible lower shaft portion;  
said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface; and  
**a dye;**

wherein said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in a tissue of the living body; and

**wherein said first passage and said second passage are sized and shaped to communicate said dye to the tissue into which the upper shaft portion is anchored.**

Applicant respectfully submits that the rejection of independent claim 1 and the respective dependent claims under this rejection have been rendered moot. Further, as to the amended claim 1, Applicant respectfully submits that *Boucher* fails to disclose, teach, or suggest at least the above emphasized claim elements.

Namely, it does not appear that *Boucher* discloses a second passage communicating with and extending outwardly from said first passage to an outer surface of said shaft, or a first passage and second passage sized and shaped to communicate a dye to the tissue into which the upper shaft portion is anchored.

Because independent claim 1 is allowable over *Boucher*, dependent claims 2-4 and 6 are allowable as a matter of law.

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**III. Claim Rejections - 35 U.S.C. § 103(a)**

**A. Rejection of Claims 1-13**

Claims 1-13 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over *Bonutti* ("*Bonutti*," U.S. Pat. 5,269,785) in view of *Boucher*. Applicant respectfully traverse this rejection.

**B. Discussion of the Rejection**

The U.S. Patent and Trademark Office ("USPTO") has the burden under section 103 to establish a *prima facie* case of obviousness according to the factual inquiries expressed in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). The four factual inquiries, also expressed in MPEP 2100-116, are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

Applicants respectfully submit that a *prima facie* case of obviousness is not established using the art of record.

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In the present case, claim 1 recites (Emphasis added):

1. A flexible tap apparatus member comprising:

a shaft having a first passage disposed axially therein, **a second passage communicating with and extending outwardly from said first passage to an outer surface of said shaft**, a flexible upper shaft portion, and a flexible lower shaft portion;  
said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface; and  
**a dye;**

wherein said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in a tissue of the living body; and

**wherein said first passage and said second passage are sized and shaped to communicate said dye to the tissue into which the upper shaft portion is anchored.**

Applicant respectfully submits that the rejection of independent claim 1 and the respective dependent claims under this rejection have been rendered moot. Further, as to the amended claim 1, Applicant respectfully submits that *Bonutti* in view of *Boucher* fails to disclose, teach, or suggest at least the above emphasized claim elements.

Namely, it does not appear that *Bonutti* or *Boucher* discloses a second passage communicating with and extending outwardly from said first passage to an outer surface of said shaft wherein said first passage and said second passage are sized and shaped to communicate a dye to the tissue into which the upper shaft portion is anchored. Thus, for at least this reason, independent claim 1 is allowable over *Bonutti* in view of *Boucher*.

Because independent claim 1 is allowable over *Bonutti* in view of *Boucher*, dependent claims 2-4 and 6 are allowable as a matter of law.

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Claim 7 recites (Emphasis added):

7. (Currently Amended) A flexible tap apparatus system comprising:

a first flexible tap apparatus member, comprising:

a shaft having a first passage disposed axially therein, **a lateral passage communicating with and extending laterally from said first passage to an outer surface of said shaft**, a flexible upper shaft portion, and a flexible lower shaft portion;  
said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface; and  
**a dye;**

wherein said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in a tissue; and

**wherein said first passage and said lateral passage are sized and shaped to communicate said dye to the tissue into which the upper shaft portion is anchored;**

wherein said shaft of said first flexible tap apparatus member comprises a first set of dimensions; and

a second flexible tap apparatus member, comprising:

a second shaft having a second passage disposed axially therein, **a second lateral passage communicating with and extending laterally from said first passage to an outer surface of said shaft**, a flexible upper shaft portion, and a flexible lower shaft portion;

said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface; and

**a dye;**

wherein said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in a tissue; and

**wherein said first passage and said second passage are sized and shaped to communicate said dye to the tissue into which the upper shaft portion is anchored;**

wherein said shaft of said second flexible tap apparatus member comprises a second set of dimensions;

wherein said first set of dimensions differs from said second set of dimensions, and wherein at least one of said flexible tap apparatus members is arranged and configured such that after insertion into a living body, said upper shaft portion of said flexible tap apparatus member is anchored in the tissue.

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Applicant respectfully submits that the rejection of independent claim 7 and the respective dependent claims under this rejection have been rendered moot. Further, as to the amended claim 7, Applicant respectfully submits that *Bonutti* in view of *Boucher* fails to disclose, teach, or suggest at least the above emphasized claim elements.

Namely, it does not appear that *Bonutti* or *Boucher* discloses a shaft with a lateral passage extending laterally from the first passage communicating with and extending laterally from said first passage to an outer surface of said shaft, or a dye that may be communicated to tissue through the passage disposed axially into said shaft through said lateral passage. Thus, for at least this reason, independent claim 7 is allowable over *Bonutti* in view of *Boucher*.

Because independent claim 7 is allowable over *Bonutti* in view of *Boucher*, dependent claims 8 and 10-11 are allowable as a matter of law.

Claim 12 recites (Emphasis added):

12. A method of creating a passage in tissue comprising:  
providing a flexible tap apparatus system comprising:  
a flexible tap apparatus member, comprising:  
a shaft having a first passage disposed axially therein,  
**a lateral passage extending laterally from said first passage to an outer surface of said shaft,** a flexible upper shaft portion, and a flexible lower shaft portion;  
said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface and;  
a dye;  
engaging said flexible tap apparatus member into the tissue;  
and  
**communicating said dye to tissue through said first passage and said lateral passage.**



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Applicant respectfully submits that the rejection of independent claim 12 and the respective dependent claims under this rejection have been rendered moot. Further, as to the amended claim 12, Applicant respectfully submits that *Bonutti* in view of *Boucher* fails to disclose, teach, or suggest at least the above emphasized claim elements.

Namely, it does not appear that *Bonutti* or *Boucher* discloses a shaft with a lateral passage extending laterally from the first passage communicating with and extending laterally from said first passage to an outer surface of said shaft, or a dye that may be communicated to tissue through the passage disposed axially into said shaft through said lateral passage. Thus, for at least this reason, independent claim 12 is allowable over *Bonutti* in view of *Boucher*.

Because independent claim 12 is allowable over *Bonutti* in view of *Boucher*, dependent claim 13 is allowable as a matter of law.

In summary, it is Applicant's position that a *prima facie* for obviousness has not been made against Applicant's claims. Therefore, it is respectfully submitted that each of these claims is patentable over *Bonutti* in view of *Boucher* and that the rejection of these claims should be withdrawn.

#### IV. Canceled Claims

As identified above, claims 5 and 9 have been canceled from the application through this Response without prejudice, waiver, or disclaimer. Applicant reserves the right to present these canceled claims, or variants thereof, in continuing applications to be filed subsequently.

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**V. New Claims**

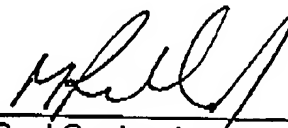
As identified above, claims 14-15 have been added into the application through this Response. Applicant respectfully submits that these new claims describe an invention novel and unobvious in view of the prior art of record and, therefore, respectfully requests that these claims be held to be allowable.

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### CONCLUSION

Applicant respectfully submits that Applicant's pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Furthermore, any and all findings of well-known art and official notice, and similarly interpreted statements, should not be considered well known since the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



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